UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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UNITED STATES OF AMERICA,

-against- Case No.: 20 CR 160 (MKV)

SETH FISHMAN, DVM, and
LISA GIANNELLI

Defendants.
----------X

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS COUNTS ONE AND TWO OF THE SUPERSEDING INDICTMENT

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I. INTRODUCTION

In a prior opinion, this Honorable court emphasized that Dr. Fishman had raised a "*serious claim about the scope of the FDCA*[1] *provisions at issue here*" and invited Dr. Fishman to brief this issue for the Court. ECF-244 at 16. Dr. Fishman and Lisa Giannelli now accept your Honor's invitation and file this Motion to Dismiss Counts 1 and 2 in the Superseding Indictment.

There are three independent grounds for the motion.

First, Counts 1 and 2 fail to allege that Dr. Fishman, Ms. Giannelli, and their alleged co-conspirators committed acts or conduct that are within the scope of the applicable federal criminal statute, Section 333(a)(2) of the FDCA. As discussed at *infra,* an agreement aimed at the distribution of misbranded and/or adulterated products with the *intent to mislead or defraud* state racehorse commissions and racetracks is not a federal crime within the scope of the felony provisions of the FDCA.

Second, application of the rule of lenity bars prosecution of Dr. Fishman and Ms. Giannelli for the conduct alleged in Counts 1 and 2.

[1] Food Drug and Cosmetic Act (FDCA).

Third, Section 333(a)(2) is unconstitutionally vague as applied to the conduct alleged in Counts 1 and 2.

II. INDICTMENT & SUPERSEDING INDICTMENT & NOVEMBER 2020 STATUS CONFERENCE

In furtherance of an effort by the FBI to ferret out bad actors in the thoroughbred horse racing industry, the Government arrested and enlisted the assistance of Dr. Fishman in October 2019 based on a sworn criminal complaint. *See* ECF-1.

Months later, in March 2020, a grand jury returned a speaking Indictment against Dr. Fishman, Ms. Giannelli and 17 others, alleging their participation in a conspiracy to violate the felony provisions of the FDCA, Sections 331(a)-(c) and (k) and 333(a)(2), and the specific offense prong of 18 U.S.C. Section 371.

On May 14, 2020, Dr. Fishman moved for a bill of particulars for, among other reasons, the absence of any facts in the Indictment identifying a specific state or federal agency, entity, person, or group of persons that was the object of the defrauding or misleading in connection with the supposed conduct comprising misbranding or adulteration pursuant to Section 333(a)(2). ECF-202. Your Honor denied that motion but also indicated that a bill of particulars may be appropriate at a time closer to trial. ECF -244 at 13-14.

More than six months later, a second grand jury returned a Superseding Indictment finding probable cause for the identical violations of the FDCA alleged in the first Indictment as to Dr. Fishman and Ms. Giannelli. Indeed, the Government again cited violations of Section 331(a)-(c) and (k) based on the specific acts of misbranding and/or adulteration supposedly found by the grand jury, including Sections 352(a), 352(b), 352(f), 352(), 351(a)(5)[2], 352(o), 353(f). ECF- 283 at 18-19 and 22-23.

In alleging violations of these provisions in Count 1, the Superseding Indictment references nebulous "state regulators" and "racing officials":

- The defendants "engaged in a corrupt scheme to manufacture, create, purchase, distribute, transport, sell, and administer a wide variety of misbranded and adulterated PEDs, as well as substances designed to ***mask the presence of PEDs from drug testing by racing and state officials.***"

ECF-283 at 11 at ¶ 16.

- "In addition to developing his [Navarro's] doping program around PEDs that are, by design, difficult or impossible for ***state regulators and racing officials*** to detect." *Id.* at 13 at ¶ 19; *see also id.* at 16 at ¶ 20d (alleging on February 13, 2019, NAVARRO instructed OAKES to visit XY Jet to administer the PED, and to lie to ***racing officials*** if necessary to access the racehorse.").

[2] The Superseding Indictment references 21 U.S.C. Section 351(a)(5) as the only basis for a charge of adulteration. That provision states that a drug is adulterated if it does not meet the conditions in 21 U.S.C. Section 360b. Section 360b, which is cited in the Superseding Indictment, is really Section 360b(a)-(q) and spans 40 pages. The first provision found at Section 360b(a)(1) is that an animal drug must be the product of an approved or conditionally approved new animal drug application (NADA) which is submitted to FDA for approval, or it will be deemed unsafe, and thus adulterated. *See* Section 360b(1)(a). For all intents and purposes, the FDA considers any animal drugs to be considered "new animal drugs."

Similarly, in Count 2, the Superseding Indictment alleges that Dr. Fishman and Ms. Giannelli acted as follows:

> SETH FISHMAN' s products were created and labeled to evade detection by ***state racing regulators,*** including with labels that contained misleading statements designed to lower the likelihood of scrutiny by regulators. SETH FISHMAN also promoted his blood building PEDs as undetectable on drug tests administered by ***state regulators and racing officials***.

Id. at 22 at ¶ 32.

At the last status conference, Your Honor asked the Government to clarify its theory:

> THE COURT: All right. Have you made any clarifications or changes with regard to the government's theory in terms of who was defrauded?

See 25:20-22 (Transcript of 11.17.20 Status Conference)

In response, the government expanded on the theory articulated in the Superseding Indictment by adding owners and competitors to the list of alleged victims:

> MR. ADAMS: With respect to misbranding, ***the racetracks, racing commissions, owners, competitors*** are all among people for whom -- or who are in the minds of the defendants charged with misleading and participating.

See 26:9-12 (Transcript of 11.17.20 Status Conference) (emphasis ours).

Nowhere does the Superseding Indictment reference "competitors" or define who those competitors would be (in Dr. Fishman's case a competitor is another

veterinarian).[3] Likewise, nowhere does the Superseding Indictment allege that "horse owners" were defrauded or mislead by Dr. Fishman or any of the other defendants in Counts 1 and 2. *Stirone v. United States*, 361 U.S. 212, 215-16 (1960) ("Ever since *Ex parte Bain*, 121 U.S. 1. was decided in 1887 it has been the rule that after an indictment has been returned its charges may not be broadened through amendment except by the grand jury itself."). The word "horse owners" is alleged only as part of Count 4, which charges different defendants with wire fraud based on false invoices provided to *horse owners*. *See* ECF-283 at 38 at ¶55. Instead, the Superseding Indictment rests on the premise that unidentified racetracks and race commissions were misled or defrauded.

IV. ARGUMENT

A. Counts 1 and 2 of the Superseding Indictment Fail to State an Offense within the Scope of Section 333(a)(2) of the FDCA and must be dismissed.

Counts 1 and2 of the Superseding Indictment fail to state an offense under Section 333(a)(2) of the FDCA because race commissions and race officials are not within the ambit of that statute.

[3] *See United States. v. Andersen*, 45 F.3d 217, 221 (7th Cir. 1995) (in a case involving the distribution of unapproved animal drugs by veterinarians, finding that "there is no reason to believe that other competitors were selling the same or similar drugs and thus suffered harm as a result of the defendants' competition.").

Federal Rule of Criminal Procedure 7(c)(1) requires an indictment to "be a plain, concise and definite written statement of the essential facts constituting the offense charged." To satisfy Rule 7(c)(1), the indictment must "fully, directly, and expressly, without any uncertainty or ambiguity, set forth all the elements necessary to constitute the offense intended to be punished," and "be accompanied with such a statement of the facts and circumstances as will inform the accused of the specific offense, coming under the general description, with which he is charged." *Hamling v. United States*, 418 U.S. 87, 117-18 (1974) (internal quotation marks omitted) (discussing constitutional minimum); *see also United States v. Pirro,* 212 F.3d 86, 91 (2d Cir. 2000) (affirming dismissal of indictment and noting that "a criminal defendant is entitled to an indictment that states the essential elements of the charge against h[er]."); (affirming dismissal where Government's proposed proof would not establish a crime within the terms of the statute); *United States v. Pacione*, 738 F.2d 567, 572 (2d Cir. 1984) (same); *United States v. Mennuti*, 639 F.2d 107, 113 (2d Cir. 1981) (same).

One reason for this requirement is to inform the defendant of "the nature and cause of the accusation," *Russell v. United States,* 369 U.S. 749, 761 (1962), so that she may prepare to challenge the evidence against her. Another is "to ensure that the prosecution will not fill in elements of its case with facts other than those considered by the grand jury." *United States v. Walsh,* 194 F.3d 37, 44 (2d Cir. 1999).

An indictment that fails to meet these baseline requirements should be dismissed for "failure to state an offense." Fed. R. Crim. P. 12(b)(3)(B)(v). "Since federal crimes are 'solely creatures of statute,' "a federal indictment can be challenged on the ground that it fails to allege a crime within the terms of the applicable statute." *United States v. Aleynikov,* 676 F.3d 71, 75-76 (2d. Cir. 2012) (citations omitted). The sufficiency of the indictment and the interpretation of a statute are both "matters of law," *id.* at 76, that can be determined prior to trial.

1. The Text of Sections 331, 352, and 305 of FDCA Illustrates that the Alleged Conduct of Defrauding or Misleading a Race Commission or Race Official is not within the Ambit of Section 333(a)(2) of the FDCA

Nowhere in the text of either the Pure Food Drug Act (1906) (the predecessor statute to the FDCA) or the FDCA (1938) is there any evidence that Congress intended federal prosecutors to use the felony provision of the FDCA to protect fair competition in thoroughbred horse racing).[4]

The text of Section 333(a)(2) is "silent as to the object of the deception." and therefore provides no guidance with respect to the contemplated victims of the deception or misleading. *United States v. Dessart*, 823 F.3d 395, 403 (7th Cir. 2016). It reads:

[4] *See* ECF-283 at 1 (alleging in the introductory section of the Superseding Indictment that "horse racing is subject to an array of state and federal regulations aimed at protecting horses and ***ensuring fair competition.")*.** At the time of the return of the Superseding Indictment, there were ***no federal regulations*** regulating horse racing. That is an incorrect statement of the law and should be stricken from the Superseding Indictment.

> Notwithstanding the provisions of paragraph (1), if any person commits such a violation after a conviction of him under this section has become final, ***or commits such a violation with the intent to defraud or mislead,*** such person shall be imprisoned for not more than three years or fined not more than $10,000 or both.

21 U.S.C. § 333(a)(2) (emphasis added).

Despite this silence, a review of the FDCA as a whole, including the prohibited acts in Section 331 and the provisions defining misbranding and adulteration in Section 352, more than amply demonstrates that Congress never intended the felony FDCA provisions to apply to the conduct alleged in Counts 1 and 2. *Deal v. United States,* 508 U.S. 129, 132 (1993) (observing that the meaning of a statutory term should not be "determined in isolation" but instead "must be drawn from the context in which it is used"); *United States v. DBB Inc.,* 180 F. 3d 1277, 1281 (11th Cir. 1999) (same); *see also Krzalic v. Republic Title Co.*, 314 F.3d 875, 880 (7th Cir. 2002) ("if the clear language, when read in the context of the statute as a whole or of the commercial or other real-world (as opposed to law-world or word-world) activity that the statute is regulating, points to an unreasonable result, courts do not consider themselves bound by 'plain meaning,' but have recourse to other interpretive tools in an effort to make sense of the statute."). Instead, the provisions were written to protect consumers and purchasers.

To start with, more-than-two-dozen misbranding provisions in Section 352 contain requirements concerning false labels, misleading advertising, and/or

inaccurate information that are designed to protect consumers or purchasers. *See* 21 U.S.C. Section 352(a)-(ff):

352 Provision	**Language of Title**
352(a)	***False or misleading label***
352(b)	**Package form; contents of *label***
352(c)	Prominence of information on ***label***
352(e)	Designation of drugs or devices by established names
352(f)	Direction for use and warnings on ***label***
352(g)	Representations as recognized drug; packing and ***labeling***; inconsistent requirements for designation of drug
352(h)	Deteriorative drugs; packing and ***labeling***
352(i)	Drug; ***misleading*** container; imitation; offer for sale under another name
352(n)	Prescription drug advertisements: established name; quantitative formula; side effects, contraindications, and effectiveness; prior approval; ***false advertising; labeling;*** construction of the Convention on Psychotropic Substances
352(p)	Packaging or ***labeling*** of drugs in violation of regulations
352(q)	Restricted devices using ***false or misleading advertising*** or used in violation of regulations
352(r)	Restricted devices not carrying requisite accompanying statements in advertisements and other descriptive printed matter
352(s)	Devices subject to performance standards not bearing requisite ***labeling***
352(u)	Identification of manufacturer (requirement of providing truthful and accurate information)
352(v)	**Reprocessed single-use devices (contains labeling requirement)**
352(w)	New animal drugs (contains labeling requirements)
352(z)	Post-market studies and clinical trials; new safety information in ***labeling***
352(bb)	***False or misleading advertisement*** or promotion of compounded drug
352(cc)	Failure to bear product identifier
352(dd)	Improper ***labeling*** of antimicrobial drugs

Many of the remaining provisions in Section 352 relate to conduct directed at the FDA, including registering with the FDA, furnishing material to the FDA, meeting specific FDA requirements, or paying fees associated with establishing a facility. *See* Sections 352(o) (registration), 352(y) (drugs subject to approved risk and mitigation regulations), 352(aa) (fees), 352(ee) (non-prescription drug requirements), and 352(ff) (unpaid fees for outsourcing facility).

Similarly, Section 351(a)(5), the only adulteration provision alleged in Counts 1 and 2, defines "adulteration" by reference to 21 U.S.C. Section 360b.[5] Much like the plain language in Section 352, the text of Section 360b(a)-(q) demonstrates that Section 360b was designed to establish registration requirements, protect consumers from unsafe drugs, and to ensure compliance with FDA regulations relating to new animal drugs, including the filing of new or conditionally approved animal drug applications. *See* 21 U.S.C. Section 360b(a)(1)-(6).

In addition to the prohibited acts constituting misbranding or adulterating found at Section 331(a)-(c) and (k), which are defined by cross-references to Sections 351-352, Section 331 of the FDCA contains more than Forty (40), other distinct "prohibited acts" which, if violated, *with the intent to defraud or mislead,* are punishable as felonies under Section 333(a)(2). On their face, the "prohibited acts" relate either to conduct directed at or likely to harm consumers[6] or conduct or

[5] 21 U.S.C. Section 360b lists more than a dozen ways in which a drug may be "adulterated" by flouting FDA regulations governing the application process for new animal drugs. Notably, Section 351(a)(5) was not originally included in the 1938 FDCA (*see* **Ex. C**) and is the only substantive adulteration provision at issue in Counts 1 and2 because the Government has alleged that the drugs were adulterated in violation of Sections 331(a)-(c) by engaging in the conduct set forth in Section 351(a)(5). ECF 283 at 18-19 and 22-23.

[6] *See e.g.* 21 U.S.C. § 331(g) (manufacturing adulterated food, drug, or device); § 331(k) (misbranding by mutilation alteration or destruction while such article is held for sale); § 331(m) (sale or offering of oleomargarine or colored margarine); 331(o)(protecting consumers and distributors by requiring paperwork); § 331(t) (part of the Prescription Drug Marketing Act, includes, as prohibited acts, importation of insulin, improper distribution of drug samples and counterfeiting of coupons); §331(w)(false statements in certificates of analyses and failure to maintain records or submit records as required by FDA); § 331(v) (introduction of dietary supplement into commerce that is unsafe); § 331(uu); § 3 (operation of facility that manufactures

acts directed at the FDA,[7] including FDA submissions and applications, FDA inspections, FDA registration requirements, FDA notifications, FDA orders, and general compliance with other FDA regulations.[8] *See also United States v. Arlen,* 947 F.2d 139, 142 (5th Cir. 1991) ("[s]everal of the twenty acts § 331 proscribes concern only the government," and therefore, after reading these provisions with

food held for sale in U.S. where owner not in compliance with hazard analysis and preventive controls); §331(ccc)(1)-(2) (mislabeling or falsification of prescriptions made in outsourcing facility); § 331(ddd) (distribution in interstate commerce of rinse off cosmetic that contains plastic microbeads).

[7] *See e.g.,* 21 U.S.C. § 331(e) (failure to permit FDA access to records and failure to make reports to the FDA); § 331(f) (refusal to permit FDA inspection); § 331(i) (false guaranty to FDA); § 331(n) (use of any FDA report provided during an inspection in labeling or advertising); § 331(p) (failure to register with the FDA)."); §331(q)(1)(B) (failure to provide paperwork); §331(r)(alteration or removal of labels which show article as detained); §331(s)(failure to make reports or retain records); §331(u)(failure to comply with orders of Secretary of FDA); §331(y)(submission of false reports to FDA related to classification of devices); §331(x)(false report to FDA regarding conformity with certain standards related to premarket approval of articles); §331(aa) (false importation record required to be maintained by FDA or provided to FDA); §331(bb) (violation of FDA order related to detained food); §331(cc)(importation of food or drugs with the assistance of persons debarred by the FDA); §331(dd) (failure to register); §331(ff) (failure to submit information to FDA in connection with importation); §331(gg) (knowing submission of false information in an inspection report); §331(ii) (falsification of serious adverse event report); §331(jj) (failure to submit information related to clinical trial or knowing submission of false information related to clinical trial); §331(mm) (failure to submit a report or provide notification); §331(nn) (falsification of a report or notification); §331(vv) (failure to comply with FDA requirements); §331(ww) (failure to comply with FDA requirements); §331(xx) (refusal to follow agency order); §331(yy) (failure to comply with FDA notification requirement); §331(zz) (failure to comply with FDA requirement of foreign supplier verification program); §331(aaa) (failure to register pursuant to FDA regulation); §331(bb) (failure to notify the Secretary in accordance with FDA regulation); §331(ccc)(3)(503b outsourcing facility failure to report adverse reporting event to FDA).

[8] Some of those provisions, much like Section 352, also contain the words misleading" or "false" in connection with submissions, statements, inspections, certificates, or information directed at or required by the FDA. *See* Section 331(i),(q)(2),(w),(y)(1),(gg),(jj)(1),(3), and (qq) (including the word "false"); *see also* Section 331(s)(2),(y)(1), and (jj)(3) (including the word "misleading").

Section 333, the FDA is the government entity mostly likely to be defrauded.); *United States v. Bradshaw,* 840 F. 2d 871, 874-75 (11th Cir. 1998) (same).

In *Bradshaw,* discussed at *infra,* the court specifically analyzed the plain text of Section 331 and found it clearly indicates that Congress contemplated the FDA as an object of Section 333(a)(2):

> As noted at the outset, 21 U.S.C. § 331 lists the acts which constitute criminal violations of the Act. Section 333(a) provides that anyone who violates a provision of § 331 commits a misdemeanor. Section 333(b) provides that "[n]otwithstanding the provisions of subsection (a) of this section, if any person commits ... such a violation [i.e., a violation of § 331] with intent to defraud or mislead ...," he commits a felony.
>
> Several of the acts § 331 prohibits concern only the government. For example, § 331(p) prohibits the failure to register with the FDA. Other examples include § 331(e) (failure to permit FDA access to records and failure to make reports to the FDA) and § 331(f) (refusal to permit FDA inspection). After reading these sections with § 333, it is clear that the FDA is the entity most likely to be defrauded under these provisions. Thus, we conclude that Congress intended the "intent to defraud or mislead" language of § 333(b) to extend to the FDA.

Bradshaw, 840 F.2d at 874-75.

The plain text of Section 305 also demonstrates that, if the FDCA contemplated anyone other than consumers as a victim of Section 333(a)(2), that victim must be narrowly construed as the FDA. That Section states in pertinent part that: "Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom

such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding." *See* Section 305 of Title 21. A similar provision is codified at 21 C.F.R. Section 7.48 (a), which requires that a person be given "appropriate notice and an opportunity to be heard" before a criminal prosecution is instituted by the FDA. *Id.* Therefore, because the plain text of the FDCA illustrates that the FDA (not some other agency) is required to provide actual notice to a possible violator of the FDCA prior to institution of criminal charges, it is indisputable that the FDA is the agency defrauded or misled by such violations.

2. Nowhere in Legislative History of the FDCA is there any Evidence that Congress Contemplated Application of Section 333(a)(2) of the FDCA to the Alleged Conspiracies in Counts 1 and2

The legislative history of the FDCA, and its predecessor statute, the Pure Food and Drug Act, demonstrate that Congress promulgated comprehensive food and drug legislation to protect the public from, among other things, false and misleading representations about the safety, efficacy, origin, or quantity of certain drugs and food**.** Newspaper articles and Congressional Reports from more than a century ago illustrate this point. *See* **Exhibits A-C and F.**

a. The 1906 Pure Food and Drug Act

The Supreme Court observed more than a century ago that the Pure Food Act which preceded the FDCA was a consumer protection act:

> The statute upon its face shows, that the primary purpose of Congress was to prevent injury to the public health by the sale and transportation in interstate commerce of misbranded and adulterated foods. The legislation, as against misbranding, intended to make it possible that the consumer should know that an article purchased was what it purported to be; that it might be bought for what it really was and not upon misrepresentations as to character and quality. As against adulteration, the statute was intended to protect the public health from possible injury by adding to articles of food consumption poisonous and deleterious substances which might render such articles injurious to the health of consumers.[9]

Congress was predominantly concerned with false or misleading labeling and the content of any labeling affixed to drugs and food. For example, in Section 8 of the 1906 Pure Food and Drug Act,[10] Congress defined "misbranding" by reference

[9] *United States v. Lexington Mill Co.*, 232 U.S. 399, 409 (1914); *see also McDermott v. Wisconsin,* 228 U.S. 115, 128, (1913) (describing the predecessor 1906 act "to exclude from interstate commerce impure and adulterated food and drugs and to prevent the facilities of such commerce to be used to enable such articles to be transported throughout the country from their place of manufacture to the people who consume and use them."); *United States v. Park,* 421 U.S. 658, 673 (1975) (describing the FDCA as protecting the consuming public by allowing the government to regulate the conditions under which drugs are manufactured and distributed). In fact, FDCA is a public welfare statute that imposes "the highest standard of care on distributors." *Smith v. California*, 361 U.S. 147, 152, 80 S.Ct. 215, 4 L.Ed.2d 205 (1959). It was enacted to enable purchasers to make intelligent choices, and, to that end, "[m]isbranding was one of the chief evils Congress sought to stop." *United States v. 45/194 Kg. Drums of Pure Vegetable Oil*, 961 F.2d 808, 812 (9th Cir. 1992).

[10] See **Exhibit A**, Pure Food and Drug Act of 1906.

to drug labels or packaging which were "false or misleading in any particular" and by reference to any drug "which is falsely branded as to the State, Territory, or Country in which it was manufactured or produced."[11] Furthermore, in that same Section of the Act, an article (food or drug) was defined as "misbranded" as follows:

- "If it be an imitation or offered for sale under the name of another article."
- "If it be an imitation of or offered for sale under the distinctive name of another article."
- "If it be labeled or branded so as to *deceive or mislead the purchaser.*" (emphasis ours).
- If a package or label "bear[s] any statement or device regarding the ingredients or the substances contained therein, which statement design or design shall be *false or misleading in any particular.*" (emphasis ours).

See **Ex. A.**[12]

One more egregious example of such mislabeling that Congress sought to prevent and punish with the passage of the Act is pictured below: [13]

[11] Members of Congress recognized this problem at that time complaining of the mis-labeling of Wisconsin Cheese as the higher quality New York cheese. https://www.visitthecapitol.gov/exhibitions/artifact/letter-franklin-macveagh-co-representative-james-r-mann-march-29-1900

[12] Similarly, a drug was deemed *adulterated* if it were sold under a name recognized by the U.S. Pharmacopeia (USP) or the National Formulary, but differed from the standard, strength, or purity as established by USP or the National Formulary. **Ex. A.**

[13] See also https://history.house.gov/HistoricalHighlight/Detail/15032393280?ret=True

Here, the packaging for a "soothing syrup" intended to treat teething children failed to advise consumers that it contained morphine. With the passage of the Act, Congress sought to prevent and punish this conduct, thereby protecting consumers.[14]

Following the Act, the Supreme Court narrowed the application of the misbranding provisions related to labeling. *See United States v. Johnson*, 221 U.S. 488, (1911). In *Johnson,* the Supreme Court, held that the Pure Food and Drug Act's misbranding provisions did not apply to false or fraudulent claims as to the curative effect of a drug "but only at such [statements] as determine the identity of the article, possibly including its strength, quality, and purity." *Johnson,* 221 U.S. at 496-97.

[14] In fact, even prior to passage of the Pure Food and Drug Act, newspaper articles reflected the public concern with inaccurate and misleading labeling. *See Washington Times,* (11/20/1904) (attached as **Exhibit B).** In an article from the *Washington Times* dated November 20, 1904, the newspaper discussed Dr. Harvey Wiley's foray into the national debate about pure food and drugs and included a section in the article labeled "public safeguarded against labels." **Exhibit B.**

Viewing the *Johnson* decision as a threat to the effective enforcement of the misbranding provisions, Congress reacted with the passage of the Sherley Amendment, which expanded the crime of misbranding to include false and fraudulent statements about the curative effects of drugs within the power of Congress to regulate.

Nonetheless, even after the amendment's passage, there were concerns about the application of the misbranding provisions to certain misleading or false statements. *Seven Cases v. United States*, 239 U.S. 510, 513-14 (1916). The issue in *Seven Cases*, was whether the Sherley Amendment applied to a defendant who shipped a cough medicine[15] interstate, along with a circular containing false or fraudulent representations about the drug as an effective preventative for pneumonia and as capable of curing Tuberculosis. *Seven Cases,* 239 U.S. at 513-14. The Court held that, it "appears from the legislative history of the act that the word `contain' was inserted in the amendment to hit precisely the case of circulars or printed matter placed inside the package, and we think that is the fair import of the provision." *Seven Cases*, at 515. The Court also addressed a constitutional challenge to the application of the statute to the circular and found that the words `false *and*

[15] (I don't think this footnote is necessary and it doesn't add much).

fraudulent' used by Congress must be given their "accepted legal meaning" which would require the government to show that "the statement contained in the package was put there to accompany the goods with actual intent to deceive, — an intent which may be derived from the facts and circumstances, but which must be established." *Id.* at 517.

b. The Food Drug and Cosmetic Act (1938)

More than 20 years later, Congress passed what is now known as the Food Drug and Cosmetic Act of 1938 (FDCA). In evaluating the proposed misbranding provisions of the new act, the Committee on Interstate and Foreign Commerce, Mr. Lea, submitted a Report to Accompany the Senate proposal, and stated:

> [It] amplifies and strengthens the provisions designed to safeguard the public health and prevent deception, and it extends the scope of the law to include cosmetics, therapeutic devices, and certain drugs that now escape regulation.

See Cong. Rept. No. 2139, 75th Congress (3d. Session) at 2, (April 14, 1938) **(Exhibit C).**

Mr. Lea then reinforced the importance of protecting consumers with a new misbranding provision:

> In order to extend the protection of consumers contemplated by the law to the full extent constitutionally possible, paragraph (k) has been inserted prohibiting the changing of labels so as to misbrand articles while held for sale after interstate shipment.

Id. at 3.

Finally, Mr. Lea stated:

> Section 502 which defines misbranded drugs and devices. In its first paragraph, it makes an extremely important contribution to existing law in defining a drug as misbranded if its labeling is false or misleading in any particular…. ***The persuasive effect of a false label on the consumer's mind is the same whether the representation is made in good faith or not***. It has been demonstrated that effective protection from the public from false labeled nostrums is in many cases impossible under this language.
> *Id.* at 7.

Mr. Lea's comments demonstrate that Congress established misdemeanor misbranding provisions without any intent requirement because it was concerned that such a requirement would stymie effective prosecution of manufacturers and distributors for false labeling under the act. Consistent with this legislative mission to protect consumers, Congress promulgated misbranding and adulteration provisions that were much broader than those contemplated or included in the Pure Food and Drug Act and that still focused heavily on misleading or false statements or representations made to the consuming public. For example, the misbranding provisions included in Section 502 (21 U.S.C. Section 352) of the FDCA were:

- Section 502(a) stated "[a] drug or device shall be deemed to be misbranded if its labeling is *false or misleading in any particular."*

- Section 502(b) deemed a drug misbranded if it did not contain labels with accurate information concerning quantity of the product.

- Sections 502(c)-(e) deemed a drug misbranded if it did not contain accurate labeling, including warnings, the name of the drug, ingredients, etc.

- Section 502(f) deemed a drug misbranded if the "label did not bear adequate directions for use."

- Section 502(i) deemed a drug misbranded if it "is a drug and its container so made, formed or filled as to be misleading or if it is an imitation of a drug or if it is offered for sale under the name of another drug."[16]

See Food Drug and Cosmetic Act (1938) (attached as **Ex. D.).**

Importantly, prior to the 75th Congressional sessions, in 1934, Representative Jenckes also introduced H.R. 7964.[17] This bill contained a provision entitled "Criminal Proceeding," which stated: In the case of a gross and willful violation highly dangerous to the public health, the penalty shall be a fine of not less than $1,000 nor more than $10,000 or imprisonment for not less than one year nor more than 3 years, or both such fine and imprisonment."[18]

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[16] What is now Section 331 also contained provisions unrelated to misbranding or adulteration. Those provisions prohibited persons from refusing to permit an FDA inspection, refusing to permit access to or copying of a record during an FDA inspection, making a false guaranty to the FDA about the receipt of misbranded or adulterated articles, and/or forging, falsely representing, or counterfeiting a label mark or stamp required by FDA regulations. *See* **Ex. D.** (Section 301(e),(f)(,(h), and (i) which are codified as 21 U.S.C. Section 331(e),(f),(h) and (i)). Each of these provisions evinces Congress' intent to punish persons who commit acts which are directed at the FDA or consumers.

[17] H.R. 7964, 73rd Cong., 2d. Sess. (1934), *reprinted* in 1 LEGISLATIVE HISTORY at 717.

[18] *Id.* at 26, *reprinted in* LEGISLATIVE HISTORY at 742.

In Introducing the bill, Representative Jenckes specifically intended to "strengthen materially" the Act in "its protection of *consumers.*"[19] She also noted that her intent was for the language in H.R. 7964 to "increase the penalties" that existed in the 1906 predecessor Act. [20]

Ultimately, Congress did not include the proposed language in H.R. 7964 in the FDCA, but it did create two tiers of criminal liability for misbranding and adulteration violations by adding the *felony* provision, at issue in this case, as Section 303 to the FDCA (21 U.S.C. Section 333(a)(2)). Under the FDCA, an article may be misbranded or adulterated pursuant to the misdemeanor provision "without any conscious fraud at all," thus creating a form of strict criminal liability. *United States v. Dotterweich,* 320 U.S. 277, 281 (1943). Felony misbranding, on the other hand, requires a showing that the defendant acted "with intent to defraud or mislead." *See* 21 U.S.C. § 333(a)(2) (emphasis added). Thus, felony liability for misbranding or adulteration requires an additional *mens rea* element that is absent from the broader-reaching misdemeanor provision.[21]

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[19] 78 CONG. REC, 2533 (1934), *reprinted in* 1 LEGISLATIVE HISTORY at 757. (attached as **Exhibit F)**

[20] *Id.* at 2534, *reprinted in* 1 LEGISLATIVE HISTORY at 758. (**Exhibit F)**

[21] Several federal courts also require a finding of materiality before a conviction under 333(a)(2) will stand. *U.S. v. Watkins*, 278 F.3d 961, 966 (9th Cir. 2002), citing *Neder v. United States*, 527 U.S. 1 (1999) ("because Congress expressly required proof of an "intent to defraud" for felony liability, we cannot infer from the absence of an express reference to materiality that Congress

In sum, throughout the entire legislative history of any of these Acts, Congress is singularly concerned with protecting consumers and purchasers. There is not a single reference to horses, horse racing, racetracks, race commissions, pari-mutuel wagering, or any other indicia that Congress intended to police the supposed anti-competitive practices of trainers, owners, or veterinarians in connection with thoroughbred horse racing.

3. No Federal Court Has Held that Race Commissions or Race Officials are Contemplated Objects of the Defrauding or Misleading Clause of Section 333(a)(2) of the FDCA.

As discussed above, federal courts have endorsed limited applications of the FDCA to conduct specifically aimed at defrauding the FDA or consumers. But no federal court has analyzed whether a race commissions or a race official is a proper object of the defrauding or misleading clause of Section 333(a)(2). And no federal court has specifically found that Section 333(a)(2) may apply to conduct aimed at masking the presence of drugs in horses from race officials or race commissions. ECF-283 at 11 at ¶ 16, 13 at ¶19, and 22 at ¶ 32.

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intended to drop that element from [§ 333(a)(2)]. On the contrary, "we must *presume* that Congress intended to incorporate materiality unless the statute otherwise dictates.""); *United States v. US USP Labs*, Criminal No. 3:15-CR-496-L., (N.D. Tex. Oct. 5, 2018) (adopting the materiality requirement for FDCA and citing *Watkins* with approval)

a. The Courts Uniformly Hold that Section 333(a)(2) of the FDCA Applies to Purchasers and Consumers

A felony misbranding or adulteration conspiracy may lie when it has, as its object, the intent to defraud consumers or purchasers. *See Hipolite Egg Co. v. United States*, 220 U.S. 45, 48-49 (1911) (interpreting the predecessor Pure Food and Drug Act of 1906 and noting that "[t]he statute is a remedial one designed to prevent frauds upon the general public, and the intention of Congress in creating the same is undoubted. *United States* v. *Freeman*, 3 How. 556, 565; Endlich, Inter. Stats., § 110."); *United States v. Cerrito*, 413 F.2d 1270, 1272 (7th Cir. 1969) (affirming a felony misbranding conviction where distributor sold counterfeit tablets to undercover agent); *United States v. Goldberg*, 538 F.3d 280, 290 (3d Cir. 2008) (vacating felony misbranding conviction for failure to prove intent to deceive consumers, but affirming that felony misbranding conspiracy can be based on theory that ultimate consumer or end user of article or drug was misled or defrauded); *see also United States v. Industrial Laboratories Co.,* 456 F.2d 908 (10th Cir.1972) (upholding a misdemeanor misbranding conviction after post-verdict application of the lesser included offense statute, finding that the government could prosecute defendants under the felony FDCA provisions for introducing adulterated drug into interstate commerce where their aim was to mislead or defraud Canadian government and Canadian firm (consignee) about their adherence to new drug testing standards established by the Canadian government and where defendants lied

to their Canadian purchasers about having performed those tests in accordance with those drug standards.).

b. Circuit Courts Hold that the Provision Applies to Schemes to Mislead or Defraud the FDA

Courts have also held that the government may allege a felony misbranding/adulteration conspiracy under the FDCA which had, as its object, the intent to defraud or mislead the FDA. *Arlen,* 947 F.2d at 143 (upholding conviction based on theory that defendant defrauded and or mislead *the FDA*); *see also U.S. v. Schraud,* No. 4:07 CR 411 CDP DDN, at *11 (E.D. Mo. Dec. 4, 2007) ("Whether or not Schraud's customers were misled or defrauded, the indictment alleges Schraud intended to defraud the FDA. The indictment alleges Schraud misbranded DXM, and that he falsely represented to the FDA that the shipments of DXM were intended for research purposes, knowing they were not")*; see also United States v. Cambra,* 933 F. 3d 752, 755 (9th Cir. 1991)[7] ("finding, in the context of applying the sentencing guidelines and the deceit and fraud language that the "intent to defraud or mislead" language in 21 U.S.C. § 333 (a)(2) may encompass both fraud on the ultimate consumer and fraud on the FDA). The defendant in *Cambra,* who was convicted of selling counterfeit products, agreed at sentencing that he "had at least the intent that the FDA not realize what he was doing, and he certainly was trying to

hide his activities from the FDA because he was worried that they certainly wouldn't approve of what he was doing." *Cambra,* 933 F. 3d at 75.

In a Fifth Circuit case, *United States v. Haga,* 821 F.2d 1036 (5th Cir.1987), involving the distribution of anabolic steroids without a prescription, the Court declined to find that Section 333(a)(2) applies to the FDA. There, the prosecution formulated a poorly worded indictment which conflated language with the 371 defraud clause and the 371 specific offense clause (alleging a felony violation of FDCA):

> That . . . JAMES R. HAGA, Jr., and other persons . . . did unlawfully, willfully and knowingly conspire . . . *to commit offenses* against the United States, *to wit, violations of the Federal Food, Drug, and Cosmetic Act,* Title 21, United States Code, Sections 301-392.
> "2. It was *a part of said conspiracy* that the defendants . . . would and did, ***with intent to defraud and mislead,*** obtain, hold, promote, market, distribute and sell anabolic steroids, androgenic hormones and other prescription human and animal drugs, and did, *with the intent to defraud and mislead,* cause the prescription drugs to be . . . sold without the authorization of a prescription . . . in violation of Title 21, United States Code, Sections 331(a), 331(k), *333(b),* and 353(b).
> ". . .
> "4. It was *a further part of the conspiracy* that the defendants . . . would and did, *with the* ***intent to defraud and mislead the FDA****, the* ***Texas State Board of Pharmacy, and the Division of Food and Drugs of the Texas Department of Health,*** *conceal and cover up their actual activities* in the following ways:

Haga, 821 F.2d at 1042. (emphasis ours).

The Fifth Circuit in *Haga* reversed the Section 333(a)(2) conviction, finding that there was an unconstitutional variance when the jury was allowed to convict the defendant of the "defraud" prong of the federal conspiracy statute -- for which he had not been indicted -- instead of the Section 333(a)(2) offense under the specific offense prong of Section 371, which was the charged violation in the indictment. *Haga,* at 1044-46.

In so holding, the Fifth Circuit recognized that felony misbranding is generally premised on an intent to defraud or mislead a purchaser, not the government. *Haga,* at 1041. Indeed, *Haga* rejected the notion that a defendant could be convicted of a felony 371 misbranding conspiracy simply because a defendant was "distributing prescription drugs in knowing violation of federal and state regulatory systems and rules." *Haga,* at 1044. The court also expressed significant reservations about the application of the *specific offense prong* of Section 371 to schemes which merely involve the non-public, deliberate avoidance of consumer protection laws (FDA regulations), reasoning that such a theory "would as a practical matter have the effect of rendering the 'defraud and mislead' language of section 333(b) mere surplusage in the prosecution of any defendant charged with a conscious (and not publicly proclaimed) violation of section 331 — only inadvertent (or publicly announced) violations of section 331 would be misdemeanors, because all

conscious (and not publicly confessed) violations would necessarily involve a deliberate evasion of established regulatory systems." *Haga*, at, 1045 n. 17.

c. One Circuit has Found that Section 333(a)(2) May Apply to a State Drug Enforcement Agency

Only the Eleventh Circuit appears to have directly addressed whether Section 333(a)(2) may apply to a state drug enforcement agency, in addition to the FDA. *United States v. Bradshaw,* 840 F. 2d 871, 874 n. 4 (11th Cir. 1998).

Bradshaw distributed steroids to his athlete clients without valid prescriptions, and the clients claimed they were defrauded or misled because he failed to apprise them of the drugs' side effects. The Government's theory was that Bradshaw defrauded or misled the FDA and *state enforcement authorities* tasked with consumer protection. More specifically, as it related to the state enforcement agency, the government contended that Bradshaw defrauded or misled *Florida state drug authorities*[22] when he was awarded a Florida drug wholesaler's permit after misleading Florida state drug authorities to believe he was an established drug wholesaler in Alabama. *Bradshaw,* at 873.

In holding that the government could proceed on this theory, the court reasoned that, "[h]aving found that the intent requirement can extend to the FDA, we have little difficulty in finding that it may extend to *state drug enforcement*

[22] The division of Drugs and Cosmetics for the Florida Department of Business and Professional Regulation is responsible for determining whether to issue drug wholesaler permits.

authorities as well." *Id.* at 875, n.9. As *Bradshaw* noted, "the state enforcement authorities work closely with federal authorities in the common goal of protecting the consumer. We do not believe that Congress could have intended to include the FDA and exclude the state drug enforcement authorities. At a minimum, we believe that Congress would have made such an odd intention explicit." *Id.* at 875, n.9.

U.S. v. Mitcheltree, 940 F.2d 1329, 1347 (10th Cir. 1991) also merits discussion. In *Mitcheltree,* the Tenth Circuit reversed the defendants' conspiracy to violate the "defraud or mislead" provision of the FDCA in a case involving the distribution of MDMA. *Mitcheltree,* 940 F.2d at 1347. In so holding, the court pronounced that "[t]he government may premise criminal liability under § 333(a)(2) based upon an intent to mislead or defraud not only natural persons, but also government agencies if there is evidence that a defendant consciously ***sought to mislead drug regulatory authorities such as the FDA or a similar governmental agency***. The case law from this circuit recognizes such a result." *Mitcheltree,* at 1347, citing *Industrial Laboratories Co.,* 456 F.2d at 910-11.

The Tenth Circuit underscored that, "if the government proceeds on this theory, there must be a demonstrated link between the § 331 violation and an intent to mislead or defraud an *identifiable* drug regulatory agency involved in consumer protection." *Mitcheltree,* at 1349, citing *Cattle King Packing,* 793 F.2d at 237-38 (defendants deliberately misbranded meat shipments by stamping false shipment

dates on the packages in violation of the Federal Meat Inspection Act to dupe the federal inspectors tasked with inspecting that meat); *Industrial Laboratories,* 456 F.2d at 910-11 (the defrauded parties were the ultimate Canadian purchaser and the Canadian government, i.e., the equivalent of the Canadian FDA.).[23] [24]

Ultimately, *Mitcheltree* articulated a baseline test for felony FDCA liability, finding that the minimum quantum of evidence the government must adduce to sustain a conviction includes: (1) "conscious involvement by the defendant with a government agency involved in consumer protection" which, sets drug standards,[25] inspects drugs,[26] regulates the use of prescription drugs,[27] or issues permits to drug

[23] There was also evidence that the defendants advised employees to move shipments of meat around to avoid detection during a federal inspection. *Id.* at 237-38.

[24] Interestingly, the FDCA contains an export exemption at 21 U.S.C. 381, immunizing such conduct from misbranding and/or adulteration liability where, among other things, the exporter meets the specifications of the purchaser. Here, although the exemption was never raised, defendant's failure to meet the specifications – by lying about compliance with Canadian drug standards – would have deprived the defendant in *Industrial Laboratories* of any protections afforded by the export exemption to the FDCA.

[25] The court cited *Industrial Laboratories,* 456 F.2d at 909.

[26] The court cited *Cattle King Packing,* 793 F.2d at 937. The defrauded or mislead party in *Cattle King* under a separate federal statute, the FMIA, was the federal agency responsible for ensuring that meat products comply with applicable federal standards. As discussed at *supra,* the FMIA contains an identical felony provision "intent to defraud or mislead" found at 21 U.S.C. Section 676(a) and a logical extension of those provisions is the federal agency, like the FDA, tasked with monitoring and ensuring the quality of meat products.

[27] The court cited *Bradshaw*, 840 F.2d at 872 and *United States v. Cerrito*,413 F.2d 1270, 1272 (7th Cir. 1969). The defrauded party in *Bradshaw* was the primary state drug enforcement agency in Florida, the Division of Drugs Devices and Cosmetics, responsible for, among other things, issuing drug permits. The statute which delegated authority to regulate drugs in Florida also specifically incorporates the FDCA. *See* Fla. Stat. Section 499.02(b) ("This part is intended

wholesalers,[28] or performs any "similar functions" and (2) any link between conscious misbranding activity and a specific intent to mislead or defraud "a government agency involving in consumer protection." *Mitcheltree*, at 1352.

d. This Circuit Recognized in Ballistrea that Courts have not Construed the "Defraud" Prong of the FDCA as broadly as its linguistically identical counterpart in Section 371

In *U.S. v. Ballistrea*, 101 F.3d 827 (2d Cir. 1996), this Circuit specifically recognized that "the concept of "defrauding" under 21 U.S.C. Section(s) 333(a)(2) has not been as broadly construed as its linguistically identical counterpart in 18 U.S.C. §(s) 371." *Id.* at 833. And, although this passage was not critical to the Court's holding, it was nevertheless significant because it distinguished the scope of conduct contemplated by the defraud prong of Section 371 (which was the charged offense in *Ballistrea)* from the specific offense prong alleging a felony violation of the FDCA (Counts 1-2 of the Superseding Indictment in this case) by recognizing that other courts have found that the specific offense prong "require[es] the Government to show actual contact between the defendant and a Government

to …. provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act.")

[28] The court cited *Bradshaw,* 840 F.2d at 873.

agency or its officials to sustain a conviction." *Ballistrea,* at 333, citing *Haga,* at 1036, 1038.[29]

e. The Cases of Rojas and Hebert are Distinguishable from the Instant Prosecution

Nationwide, the defense has identified just two cases where the government has used Section 332(a)(2) to prosecute state race violations: *United States v. Hebert*, No. 18-30321 (5th Cir. Mar. 26, 2019) and *United States v. Rojas*, No. 19-2056, at *13 (3d Cir. Jan. 11, 2021). Both cases are distinguishable, most notably because neither defendant raised any of the same challenges pre-trial, at trial or on appeal which are presented in this motion.

In *Hebert*, No. 18-30321, at *3, the defendant was an administering veterinarian with a pari-mutuel license. The Fifth Circuit denied each of the defendant's challenges, including the same challenge he raised on a motion to dismiss pre-trial that the animal drugs (dermorphin) were not misbranded or adulterated under the FDCA because they were not new animal drugs as defined by the FDCA under Section 321(v).

[29] Importantly, *Ballistrea* left for another day whether the court in *Haga* would have even concluded that *Ballistrea's* conduct involving "active concealment and evasion" from the FDA which amounted more than "inadvertent contact with a governmental agency or incidental infringement of government regulations" was sufficient to affirm a conspiracy to defraud conviction, let alone a conspiracy based on a violation of Section 331(a)(2) of the FDCA, to stand. *Ballistrea,* at 834, n.3, citing *Haga,* at 1401.

In *Murray,* the defendant was a trainer with a pari-mutuel license. In a single page from the *Murray* decision from last month (prior to the alleged conduct in this case or the return of the Superseding Indictment), the Third Circuit found that it was not error to *sentence* the defendant in *Murray* under the felony misbranding provision because she knew and directed veterinarians to administer prohibited substances and to file falsified reports on race day. *Rojas*, No. 19-2056, at *13.

Neither case directly addressed the issues raised by this motion, including whether the grand jury has returned an allegation of an actual *federal crime* under Section 333(a)(2) based on the allegation that trainers and veterinarians and others agreed to "evade detection," a state race commission or race officials by misleading or defrauding those race commissions or officials.

6. Application of the Section 333(a)(2) Jurisprudence to the Instant Case

Collectively, these cases demonstrate the Government's failure to state a crime even under the broadest construction of the FDCA's felony provisions. *See* Fed. R. Crim. P. 12(b)(3)(B)(v). Most courts that have specifically evaluated Section 333(a)(2) have held that the Section may apply to *consumers* and the *FDA*. The farthest any court has been willing to specifically extend Section 333(a)(2)– through any type of reasoned analyses – was to the FDA's state counterpart in *Bradshaw,* the Florida FDA. *Bradshaw,* at 874-75. Likewise, in *Mitcheltree,* the Tenth Circuit appeared to establish the minimum quantum of evidence the

government must adduce to sustain a Section 333(a)(2) and pronounced that "there must be a demonstrated link between the § 331 violation and an intent to mislead or defraud an *identifiable* drug regulatory agency involved in consumer protection." *Mitcheltree,* at 1349. *Mitcheltree* also seemed to suggest that an agency could be considered a "government agency involved in consumer protection" if the agency performs functions which are substantially similar to the functions performed by the FDA. *Id.* at 1352.

In the instant case, an examination of state race commissions and state racetracks further supports our argument. There are unmistakable differences between the multiple core functions performed by state race commissions and racetracks and the core functions performed by the FDA or a state drug enforcement agency.

(i) State Race Commissions Perform Core Functions as Instrumentalities of the State which are separate and distinct from the functions performed by the FDA

Racehorse commissions and racetracks ensure fair competition in horse racing. They are not responsible for or concerned with protecting consumers or public health. Nor do they perform any of the following functions as instrumentalities of the state: inspecting manufacturers, distributors, wholesalers and/or pharmacies, establishing new drug standards, establishing labeling and/or advertising requirements, monitoring the safety or efficacy of approved drugs,

approving applications for new drugs, and/or issuing drug permits (*e.g.* wholesale drug permits).

The New Jersey Racing Commission[30] is focused almost exclusively on ensuring fair competition. *See* N.J. S.A. Section 5:5-22 (establishing a NJ Race Commission vested with the powers to regulate pari-mutuel wagering and horse racing); N.J.A.C. Section 13:70-1-32 (establishing the rules of the NJ Race Commission).; N.J.A.C. Section 13:70-1.1("These rules are to apply to all tracks, all race meetings and to all persons and all matters within the jurisdiction of the New Jersey Racing Commission.").

The "About Us" page for the N.J. Racing Commission states:

> The New Jersey Racing Commission is responsible for regulating the safety and integrity of the horse racing industry through the conduct of investigations, prosecutions and via regular monitoring. ***The Division of the New Jersey Racing Commission has jurisdiction over New Jersey's thoroughbred and standardbred permit holders*** and the authority to regulate racing at the state's three racetracks.
>
> Activities included in the regulation of racing activities are the oversight of pari-mutuel wagering, supervising pari-mutuel operations at all the tracks and granting permits for the conduct of running the thoroughbred and standardbred race meetings in the state where pari-mutuel wagering is allowed. In 2016, the three operating racetracks in New Jersey scheduled 271 live racing dates. The Commission also has jurisdiction over the simulcasting of horse racing activities at these racetracks as well

[30] This is but one of many racehorse commissions governed by distinct laws and regulations.

> as casino simulcasting facilities, the Account Wagering System and six Off-track wagering facilities.[31]

The Commission also monitors the conduct of every race conducted at its three racetracks, incorporates a permitted medications schedule for thoroughbred horses and harness racing established by a private scientific community (ARCI), supervises the betting activity associated with those races, and collects pari-mutuel taxes. [32]

The New York Gaming Commission regulates, among other things, horse racing in New York through its Division of Horse Racing and Pari-Mutuel Wagering. The Rules and Regulations Chapter 1 (Division of Horse Racing and Pari-Mutuel Wagering), Subchapter A, Thoroughbred Racing, 9 NYCCR Sections 4000-4082.3 circumscribe the "thoroughbred racing rules and regulations of the New York State." In the definitional section, Section 4000.3 defines the "rules and regulations" as "all rules of the commission applicable to administration and racing unless other meaning is clearly indicated." *See* 9 NYCCR Sections 4000.3(g).

The pari-mutuel system in New York has been explained in *Aliano v. Westchester Racing Ass'n*, 265 App.Div. 225, 38 N.Y.S.2d 741, wherein the Appellate Division, Second Department, in an opinion stated:

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[31] https://www.nj.gov/oag/racing/about.html

[32] *Id; see also* https://www.njleg.state.nj.us/2020/Bills/S1000/541_I1.HTM

> 'Pari-mutuel betting differs from the personal transaction between a bookmaker and a bettor, in which the agreement to pay winnings is made on the personal responsibility of the bookmaker. Under the pari-mutuel system every bettor contributing to the mutuel pool becomes in effect a bookmaker for every other bettor and the pool so constituted is responsible for payment of winnings. The racing association is the administrative agent for the collection and distribution of the pool and presentation to it of a ticket for payment from the sum deposited in the pool is essential to the proper conduct of that system of betting.'

Shapiro v. Queens Cty. Jockey Club, 184 Misc. 295, 302, 53 N.Y.S.2d 135, 140–41 (N.Y. Mun. Ct. 1945).

The New York Gaming Commission also regulates charitable games, like bingo, video lottery gaming, casino gaming, games of chance (raffle, bell jar, etc.), interactive fantasy sports, and account wagering. Thus, the predominant purpose of the Gaming Commission is to regulate and ensure the integrity of various gambling activities in New York.

Florida, much like New York, does not have a racehorse commission. Instead, rules are promulgated through the Florida Division of Parimutuel Wagering, which is a division of the Florida Department of Business and Professional Regulation and part of the executive branch in Florida.[33] The Division has promulgated a comprehensive regulatory framework for monitoring pari-mutuel wagering and

[33] http://www.myfloridalicense.com/DBPR/pari-mutuel-wagering/

horse racing. *See, e.g.,* Fla. Admin. Code Section 61D-6.008, 61D-6.011 and Fla. Stat. Section 550.24515(7)(a); *see also Solimena v. Florida Department of Business and Professional Regulation*, 402 So. 2d 1240, 1247 (3rd DCA Fla. 1981) ("The purpose of chapter 550 is to regulate and control racing in Florida in accordance with appropriate standards of conduct, a function of police power.").

Each of these Commissions or Divisions performs another core state function by collecting state tax revenues. *See* Fla. Stat. Section 550.135 (2) (all funds in excess of 1.5M in the Pari-Mutuel trust wagering fund are deposited into General Revenue Fund); N.J.S.A. Section 5:5-68 (all monies received by Race Commission shall be paid into the State treasury except money deposited into NJ Horse Breeding and Development Account); N.Y. CONST, Article I, Section 9 ("pari-mutuel betting on horse races as may be prescribed by the legislature and from which the state shall derive a reasonable revenue for the support of government"); *see* 9 NYCCR Section 4009.27 ("Every corporation, association or nonprofit racing association shall pay to the New York State Thoroughbred Breeding and Development Fund the percentage of the pari-mutuel pool as required by law.").

In sum, the core legislative purpose of these state instrumentalities is to monitor wagering, pari-mutuel operations, and fair competition. They are not, however, concerned with consumer protection. Nor are they concerned with

regulating interstate flow of drugs, regulating permit holders of specific drugs, approving drugs, or regulating and monitoring the efficacy and safety of drugs.

(ii) *Racehorse Commissions Perform and Enforce their Medication Administration Regulations without Drawing Distinctions between Unapproved or Approved Drugs and instead focus on the timing of the administration of permitted medications established by private scientific associations.*

Beyond these critical differences between the FDA and state racing commissions, the state race regulations governing the administration of medication to thoroughbred horses fail to draw any distinctions between the use of FDA approved or unapproved drugs. Unlike the FDA, racehorse commissions and racetracks do not regulate or approve drugs, dictate whether a drug is safe for its intended use, or determine whether a prescribed use of a drug is an "extra-label" use.

Instead, the state commissions and their employees test for the presence of drugs in *trainers* and *horses* and *administering veterinarians.* More importantly, the commissions regulate *when* a drug may be administered to a thoroughbred prior to a race. Sometimes that threshold is 96 hours. Sometimes it is 48 hours. Sometimes it is 24 hours. It depends on the drug. *See* N.J Admin. Code, 13:70-14A1(b)*; see also* 9 NYCCR, Section 4043.2(c)-(g); Fla. Admin. Code Section 61D-6.008 and 61D-6.011.

In New Jersey, for example, the rules prohibit a horse from "carrying in its body any drug or substance foreign to the natural horse" on race day with the

exception of "external rubs and innocuous compounds". *See* N.J Admin. Code, 13:70-14A1(b). The rules also specifically incorporate the Association of Racing Commissioners International (ARCI) Controlled Therapeutic Medical Schedule for determining the quantity and timing of administration of any drug or substance. *Id; see also* 9 NYCCR, Section 4043.2(c); Fla. Admin. Code Section 61D-6.008 and 61D-6.011.

In stark contrast to the FDA, the state commissions specifically *disallow* the administration of FDA-approved animal drugs at certain times, even if such drugs are necessary for the treatment of the animal and are prescribed by a licensed veterinarian. *See* 9 NYCCR, Section 4043.2(c)(1)-(8) (listing FDA approved drugs which cannot be administered to a competing thoroughbred 24 hours before a race, including omeprazole electrolytes, vitamins, food supplements, "or other drugs")[34];

[34] New York also authorizes the administration of Human Chorionic Gonadatropin (HcG) prior to a race although, based on the undersigned's research to date, the FDA has only approved NADA's, as of today, for 3 products which contain HcG and the only approved uses relate to broodfish, cows, and swine to treat among other things, nymphomania. NYCCR, Section 4043.2(d)(9). Further, HcG does not appear as an active ingredient for any of the current approved new animals drug applications on FDA's website. *See* **Exhibit E (**List of Approved Animal Drug Applications last visited January 17, 2021). As such, New York's racing framework appears to directly contravene FDA regulations. Similarly, Furosemide, which is incorrectly listed as "Lasix" instead of "Salix, is available in tablets, syrup, or injectable and is regulated by the race commissions if there is a single incident of bleeding. *See* 9 NYCRR Section 4043.2(b)(1); *see also* ARCI Controlled Therapeutic Medical Schedule (2019), incorporated in N.J Admin. Code, 13:70-14A1(b); *see also* ARCI Controlled Therapeutic Medical Schedule (2014), incorporated in Fla. Stat. Section 550.24515(7)(a) and Fla. Admin Code. Section 61D-6.011. Yet, the FDA has never expressly approved the use of Furosemide in horses for anything other than the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory. https://animaldrugsatfda.fda.gov/adafda/views/#/home/searchResult (last visited 2.3.21). The NY

N.J Admin. Code, 13:70-14A1(b) (listing examples of prohibited foreign substances on race day including among other things "anti-inflammatories" (e.g. NSAIDs); *see also* ARCI Controlled Therapeutic Medical Schedule, incorporated in N.J Admin. Code, 13:70-14A1(b) (listing a host of FDA approved drugs, including guaifenesin,[35] omeprazole, prednisolone, among others, as prohibited drugs at specific times before a race); *see* Fla. Admin. Code Section 61D-6.008(2)(s) and (v)(prohibiting the presence of FDA approved drugs in the body of a competing thoroughbred, including, among other approved drugs, omeprazole and triamcinolone acetonide). Such strict prohibitions against the administration of any substance which is foreign to the horse's body therefore necessarily include the administration of FDA approved drugs, like Omeprazole,[36] among others, which, by definition, cannot be misbranded or adulterated under Section 352 of the FDCA, and

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Gaming Commission also permits the use of furosemide if there is at least *one occasion* of bleeding and the FDA has never approved Furosemide for the treatment of EIPH (exercise-induced pulmonary hemorrhage).

[35] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021282Orig1s048lbl.pdf; this is a common drug used to treat colds and is found in products like Mucinex which are over the counter, non-prescription drugs.

[36] Omeprazole is the active ingredient found in Prilosec. It can be purchased Over the Counter and without a prescription. https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/questions-and-answers-prilosec-otc-omeprazole#:~:text=Both%20prescription%20Prilosec%20and%20Prilosec,only%20symptoms%20of%20frequent%20heartburn.

lidocaine products, rubs, caffeine, or vitamins.[37] *See* 9 NYCCR, Section 4043.2(c)(1)-(8) and N.J Admin. Code, 13:70-14A1(b).

In short, the race commissions have adopted a markedly different approach to drugs than the FDA.

7. The Horseracing Safety and Integrity Act of 2020 Gives the FTC Plenary Authority over Horse Racing.

The legislative history and the text of the recently-signed-into-law Horseracing Safety and Integrity Act (HSIA) shows that Congress never intended the alleged conduct in Counts 1 and 2 of "horse-doping" to fall within the ambit of Section 333(a)(2) of the FDCA.[38]

The HSIA gives the Federal Trade Commission (FTC), not the FDA, the plenary authority to oversee a national, comprehensive anti-doping and medication control program for racehorses. *See* **Exhibit G.** This is a logical role for the FTC because it is tasked with policing *unfair competition.*[39] The HSIA also obligates the medication board to either permit the U.S. Anti-Doping Association to oversee and

[37] Vitamins are substances that the FDA has deemed dietary supplements, *i. e.* not drugs. *See* 21 U.S.C. Section 321(ff)(1)(A) and (D).

[38] *Deep Within Relief Bill Horse Racing Gets New Tools to Clean Up,* Joe Drape, New York Times (12/29/20); available at https://www.nytimes.com/2020/12/29/sports/horse-racing/horse-racing-doping-usada.html

[39] https://www.ftc.gov/enforcement/anticompetitive-practices

monitor doping or to delegate this monitoring function to an equally qualified anti-doping and medication control agency or association.

The Act itself contains *no criminal provisions*. Violations of the Act – including violations related to "doping"– are considered ***civil violations*** punishable by sanctions and ***civil monetary penalties***.

Thus, Congress' assignment of the FTC as the agency responsible for creating a medication board to oversee doping in horse racing, and the absence of any criminal provisions in the HSIA demonstrates that Congress never intended for the FDA, or any other drug enforcement agency tasked with the performance of similar functions, to regulate or sanction unfair competition in horse racing through the application of the FDCA felony misbranding provisions. Rather Congress intended to sanction horse-doping through civil and administrative penalties.

In conclusion, Counts 1 and 2 of the Superseding Indictment fail to state an offense within the scope of Section 333(a)(2) of the FDCA. As shown herein, this conclusion is further buttressed by the statutory text of FDCA, its legislative history, and the absence of any controlling judicial decisions regarding the application of Section 333(a)(2) to the alleged conduct in Counts 1 and 2.

Thus, a dismissal of Counts 1 and 2 in the Superseding Indictment is warranted.

B. THE RULE OF LENITY BARS PROSECUTION OF DR. FISHMAN AND MS. GIANNELLI FOR VIOLATIONS OF THE FELONY FDCA PROVISIONS

The Supreme Court has repeatedly recognized the longstanding principle of lenity, which requires courts to resolve any "ambiguity concerning the ambit of criminal statutes" in the defendant's favor. *Yates v. United States*, 135 S. Ct. 1074, 1088 (2015) (plurality opinion) (citation omitted); *see, e.g., Skilling v. United States*, 561 U.S. 358, 410 (2010) *United States v. Santos*, 128 S. Ct. 2020 (2008) (citing *United States v. Bass*, 404 U.S. 336, 347-349 (1971)) (reversing a money laundering conviction based on the rule of lenity and emphasizing that the rule of lenity requires "ambiguous criminal laws to be interpreted in favor of the defendants subjected to them.").

The rule of lenity acts as a tiebreaker in instances where, even after looking to traditional canons of interpretation, a court must "simply guess" where Congress intended to draw the line between innocence and guilt. *Barber v. Thomas*, 130 S.Ct. 2499, 2508-09 (2010). In other words, when a criminal statute has two possible readings, courts must not "choose the harsher alternative" unless Congress has "spoken in language that is clear and definite." *Bass*, 404 U.S. at 347-349; *United States v. Thompson/Center Arms Co.*, 504 U.S. 505, 513 (1992) (applying rule of lenity and emphasizing that "[n]either the statute's language nor its structure provides any definitive guidance"); *Ladner* v. *United States*, 358 U.S. 169, 178

(1958) ("This policy of lenity means that the Court will not interpret a federal criminal statute so as to increase the penalty that it places on an individual when such an interpretation can be based on no more than a guess as to what Congress intended."); *Prince* v. *United States*, 352 U.S. 322, 329 (1957) (emphasizing that the doctrine is one "of not attributing to Congress, in the enactment of criminal statutes, an intention to punish more severely than the language of its laws clearly imports in the light of pertinent legislative history.").

The rule of lenity also safeguards separation of powers and fairness principles by ensuring that "[i]t is the legislature, not the Court, which is to define a crime, and ordain its punishment." *United States v. Wiltberger*, 18 U.S. 76, 95 (1820). And, by applying the rule of lenity, judges "provide an institutional check on the political excesses that permit unclear laws, prosecutorial overreach, and infringements on liberty." *See* Intisar A. Rabb, Appellate Rule of Lenity, 131 Harv. L. Rev. F. 179, 181-82 (2018) (explaining that the rule "lies at the heart of interpretive questions in the criminal justice arena"); *Liparota v. United States*, 471 U.S. 419, 427 (1985) ("Application of the rule of lenity . . . strikes the appropriate balance between the legislature, the prosecutor, and the court in defining criminal liability.").

In the instant case, the rule of lenity bars prosecution of Dr. Fishman and Ms. Giannelli under Section 333(a)(2) for his alleged defrauding or misleading of race commissions and race officials.

A decision from the Fifth Circuit, *United States v. Grissom,* 645 F. 2d 461 (5th Cir. 1981), mandates this conclusion. In *Grissom,* the Fifth Circuit reversed a conviction under 18 U.S.C. 658 (an agricultural fraud offense) based on application of the rule of lenity to a statute which, as here, was silent as to the object of the "intent to defraud." There, the Government prosecuted a soybean farmer under Section 658 for willfully disposing of any property mortgaged, pledged to, or held by the Secretary of Agriculture under the theory that the farm intended to defraud his landlord. *Grissom,* at 465-65. Section 658 states:

> Whoever, with intent to defraud, knowingly conceals, removes, disposes of, or converts to his own use or to that of another, any property mortgaged or pledged to, or held by, . . . the Secretary of Agriculture acting through the Farmers' Home Administration . . . shall be fined not more than $5,000 or imprisoned not more than five years, or both.

In deciding whether to affirm the conviction under Section 658, Honorable Judge Irving Goldberg rejected the government's argument that the omission of any identifiable victim in the statute implied that "with intend to defraud" in Section 658 could apply to any victim, reasoning that:

> By its terms § 658 is silent as to who the intended victim of the fraud must be in order to constitute a violation. Although the government argues that the omission of an intended victim within the statute is dispositive of the case, we find the statutory silence to be wrought with ambiguity. Based solely on the words of the statute, ***it is impossible to intuit whether Congress meant to punish only those who sought to defraud the government, those who intended to defraud any party whom the federal government has an interest in protecting, or those who intend to deceive anyone at all***. Moreover, neither the cases decided under § 658 nor the

> legislative history of the statute shed any light on the proper interpretation of the "intent to defraud" requirement.

Grissom, 645 F.2d at 465-66. (emphasis ours).

In so finding, Judge Goldberg underscored that application of the rule of lenity mandated a reversal of a Section 658 conviction where, as in *Grissom,* the conviction was premised on defrauding defendant's landlord:

> However, an application of principles of statutory interpretation and a commonsense appraisal of § 658 lead us to conclude, with much conviction, ***that the statute should not be read to cover the situation of a sharecropper acting solely to defraud his landlord, simply because the crops used in committing such fraud happened to be mortgaged to the FHA.*** The first interpretative principle and one to which the Supreme Court has repeatedly paid tribute provides that "ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity."

Grissom, at 465-66. (emphasis ours)

In reversing the conviction, the court in *Grissom* also highlighted how critical it was for the court to apply lenity when there was no indication from legislative the history surrounding Section 658 that Congress ever intended to punish persons for defrauding their landlords: "Thus, before we risk sending a sharecropper to a federal prison for committing a federal felony offense by acting to defraud his landlord, we must be sure that Congress intended such a result." *Id.* at 466.

Applying the reasoning in *Grissom* here, the FDCA felony provisions should not be read to apply to a veterinarians or trainers who have allegedly defrauded a state race commission. *Id.* at 465-66. "This principle is supported not only by the

virtue of longevity, but by the compulsion of logic and the desire for the fair treatment of the citizenry" and "ensures that "a fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed. To make the warning fair, so far as possible the line should be clear." *Id.* at 466.

United States v. Smith, 740 F.2d 734, 738-39 (9th Cir. 1984) also supports the application of the rule of lenity. In *Smith*, the Government alleged that defendant (a clinical investigator) violated Section 331(e) of the FDCA which makes it a crime to fail to maintain records required under 21 U.S.C. § 355(i). The Government's prosecution rested on the novel theory that Section 355(i) applies to clinical investigators as well as manufactures and sponsors of clinical investigations. The Ninth Circuit dismissed the indictment. The court reasoned that neither the words of the FDCA nor the legislative history supported the government's construction of the FDCA and reinforced:

> Our concern for the protective purposes of remedial legislation, however, ***does not vest this court with a license to rewrite the statute***, for "our problem is to construe what Congress has written. After all, Congress expresses its purpose by words. It is for us to ascertain — neither to add nor to subtract, neither to delete nor to distort." *62 Cases, More or Less, Each Containing Six Jars of Jam v. United States,*340 U.S. 593, 596, (1951) (misbranding prohibition not applicable to product labeled "imitation" jam). "Our compass is not to read a statute to reach what we perceive — or even what we think a reasonable person should perceive — is a `sensible result'; Congress must be taken

> at its word unless we are to assume the role of statute revisers." *Bifulco v. United States,*447 U.S. 381, 401 (1980) (Burger, C.J., concurring).

Smith, 740 F. 2d at 734, 738-39 (emphasis ours)

Thus, here, just as in *Grissom* and *Smith,* application of the rule of lenity is warranted. In fact, if the felony provisions of the FDCA were to apply to state racehorse commissions or racetracks--where neither the text history, or purpose of the FDCA reveal that Congress intended Section 333(a)(2) to apply to such conduct-- it would permit prosecutors to draw arbitrary lines regarding the scope of penal statutes. *Santos*, 553 U.S. at 519 (plurality opinion) ("We interpret ambiguous criminal statutes in favor of defendants, not prosecutors"); *Kirby*, 74 US 48; *Grissom,* at 465-66.

C. THE VOID FOR VAGUENESS DOCTRINE BARS PROSECUTION OF DR. FISHMAN AND MS. GIANNELLI FOR THE CONDUCT ALLEGED IN COUNTS ONE AND TWO OF THE SUPERSEDING INDICTMENT

"It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined." *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). The Supreme Court writes that a law must give a person of ordinary intelligence a reasonable opportunity to know what is prohibited, and that "laws must provide explicit standards for those who apply them." *Grayned*, 404 U.S. at 408 In other words, the language of a statute must

clearly define the illegal conduct, and it must clearly define how law enforcement officials are to determine when the law is being violated, leaving no discretion in their hands.

This second element, the arbitrary enforcement element, is at issue in this case, and is viewed as the more essential, in light of the inherent harms posed by "a standardless sweep [that] allows policemen, prosecutors and juries to pursue their personal predilections." *Kolender v. Lawson*, 461 U.S. 352, 358 (1983). "A vague law impermissibly delegates basic policy matters to policemen, judges, and juries for resolution on an ad hoc and subjective basis, with the attendant dangers of arbitrary and discriminatory application." *Grayned,* 408 U.S. at 108-09; *see also United States* v. *Reese*, 92 U.S. 214, 221 (1876) ("It would certainly be dangerous if the legislature could set a net large enough to catch all possible offenders and leave it to the courts to step inside and say who could be rightfully detained, and who should be set at large. This would, to some extent, substitute the judicial for the legislative department of government."). [40]

[40] The doctrine of vagueness also ensures that statutes are not interpreted in a way "***lead[s] to injustice, oppression or an absurd consequence***." *United States v Kirby*, 74 US 482, 485-87 (1869) (emphasis ours) (holding that "the act of Congress which punishes the obstruction or retarding of the passage of the mail, or of its carrier, does not apply to a case of temporary detention of the mail caused by the arrest of the carrier upon an indictment for murder"); *See also United States* v. *Jin Fuey Moy,* 241 US 394 (1916) (finding absurdity when defendant was indicted for a conspiracy "to have in . . . possession" of another person, not registered, a quantity of opium, in violation of the Opium Registration Act of 1914, which declared it unlawful for "any person" who had not registered and paid the prescribed tax, to have in his possession or control any of the drug

Here, application of Section 333(a)(2) to Dr. Fishman's alleged conduct of defrauding or misleading race officials or race commissions renders the statute unconstitutionally vague in violation of the due process clause of the U.S Constitution. *Kolender,* 461 U.S. at 358. In fact, the Government's proffered construction of the FDCA empowers federal prosecutors, not Congress, to arbitrarily pick and choose when a *felony provision* – never envisioned by Congress– might apply to future conduct they view as morally repugnant. *Id.* at 358; *see also Mitcheltree,* at 1349 (reinforcing that "[d]istributing drugs in knowing violation of federal and state regulatory systems and rules is too general" to support a Section 371 alleging a violation of the defraud and mislead clause of the FDCA).

Compounding this problem, the supposed misleading or defrauding under the FDCA rests entirely on the general *non-criminal* obfuscation of state rules regulating

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in question reasoning that the words "any person not registered" could not be taken to apply to any person in the United States, but must be read in harmony with the purpose of the Act, to refer to persons required by law to register); *United States* v. *Palmer,* 16 US 610 (1818) (Marshall J.) (finding application of statute criminalizing piracy on the high seas to a person to be absurd and holding held that "the words "any person or persons," although broad enough to comprehend every human being, could not, in view of the exceptional consequences of a literal application, and the intent of the legislature, as derived from the title of the Act and a reading of the whole statute, be construed to apply to persons, not citizens, who committed offenses on foreign vessels on the high seas."); *Marks v. United States,* 430 U.S. 188, 191–192 (1977) (reversed a conviction under a state obscenity law because it rested on an unforeseeable judicial construction of the statute and thus reversal was mandated because affected citizens lacked fair notice that the statute would be thus applied); *Bouie v. City of Columbia*, 378 U.S. 347 (1964) (a case involving the cognate provision of the Fourteenth Amendment, the Court reversed trespass convictions, finding that they rested on an unexpected construction of the state trespass statute by the State Supreme Court).

horse racing[41] and some of those rules[42] are vague themselves and should be strictly construed. *Whitaker v. Department of Insurance & Treasurer,* 680 So.2d 528, 531 (Fla. 1st DCA 1996) ("statutes that pose the risk of license sanctions must be strictly construed in determining whether they violate the due process clause of the Florida Constitution based on vagueness concerns.").[43] Florida in fact has invalidated a permitted medication rule as unconstitutionally vague. *See Simmons v. Division of Pari-Mutuel, Etc.,* 412 So. 2d 357, 359 (Fla. 1981) ("we hold that the clause, 'any substance which is foreign to the natural horse or dog,' as it appears twice in section 550.241, lacks a rational basis and is unconstitutional and void.").

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[41] *See* 26:9-12 (Transcript of 11.17.20 Status Conference)

[42] *See* 9 NYCCR, Section 4043.2(c)-(g); Fla. Admin. Code Sections 61D-6.008 and 61D-6.011; N.J Admin. Code, 13:70-14A1(b).

[43] State courts have not hesitated to invalidate administrative laws governing suspension or sanctions on vagueness grounds. *Tuma vs. Board of Nursing,* 593 P.2d 711, 717 (Idaho 1979)(finding that the statute cannot "withstand scrutiny for vagueness *as applied* to the specific conduct here made the basis of Tuma's license suspension"); *Pennsylvania State Board of Pharmacy v. Cohen,* 448 Pa. 189, 292 A.2d 277, 282 (1972) (holding that the grounds to revoke a pharmacist's license for "grossly unprofessional conduct" must be limited to those further spelled out in the statute or in rules, because "revocation of licenses and permits for conduct not specifically defined or prohibited by the statute, would render the statute unconstitutional on grounds of vagueness in violation of the Due Process Clause of the Fourteenth Amendment."); *Watkins, DDS vs, StateBoard of Dentistry,* 740 A.2d 760 (Pa. Cmwth. 1999) (finding that suspension for unprofessional conduct based on dentist failure to ensure that his office contained "appropriate monitoring equipment" for administration of general anesthesia was void for vagueness); *Chaby v. State Board of Optometrical Examiners*, 386 A.2d 2071 (Pa. Cmwth 1978) (vacating optometrist suspension finding that provision relating to "incompetency" posed vagueness concerns); *Nelson, DVM vs. State Board of Veterinary Medicine,* No. 1216 C.D. 2004 (Pa Cmwth Dec. 7, 2004) (vacating public reprimand against veterinarian based on Board's finding that his conduct was professional incompetent reasoning that the Board's interpretation ran the risk of rendering the rule void for vagueness).

In sum, adopting the Government's tortured construction of an ambiguous statutory provision in this case would encourage courts to fill in gaps and to divine a Congressional intent where none exists. But, perhaps more importantly, acceptance of such a broad construction sends a message to the government that courts are willing to interpret statutes in a way that accommodates an individual prosecutor's objective of obtaining felony convictions. *Lanier*, 520 U.S. at 266.[44]

The risk of doing so here is plain because, with this prosecution, the government seeks to lay down a precedent. Under this precedent, if any veterinarian, trainer, or person happens to use, receive, deliver, or supply a "misbranded" drug in connection with a horse race, they may now wind up as a defendant in a federal criminal prosecution. Moreover, such a dangerous precedent opens the door to federal prosecutions of professional athletes who are caught "doping" by using misbranded drugs or prosecutions of athletes who cheat (*see e.g.*, Tom Brady "Deflate-Gate" and the Houston Astros' signal stealing debacle) even though, just like horse racing, there are already administrative proceedings which adjudicate these matters by issuing fines and suspensions and sometimes even a "ban." This could not have been the intent of Congress when it passed the FDCA. Such a

[44] See also *Three Felonies a Day,* Harvey Silvergate, Encounter Books, (2009) available at (https://www.amazon.com/Three-Felonies-Day-Target-Innocent/dp/1594035229 (describing how prosecutors may use criminal statutes to convert run of the mill conduct into felonies); *see Sorich v. United States,* 555 U.S. 1204 (1999) (SCALIA, J. dissenting) ("It is simply not fair to prosecute someone for a crime that has not been defined until the judicial decision that sends him to jail.")

prosecution violates our baseline principles of fairness and due process envisioned by our founders.

For these reasons, Counts 1-2 in the Superseding Indictment must be dismissed.

CONCLUSION

The offense conduct alleged in Counts 1and 2 simply does *not amount to federal criminal conduct* under Section 333(a)(2) of the FDCA. To find otherwise would require this Court to rewrite legislative history, to arbitrarily fill in textual gaps, and to divine a Congressional intent to include race commissions and race officials within the ambit of Section 333(a)(2) where none exists. To find otherwise would severely undermine bedrock principles of due process, fair notice, and federalism, which were critical to the founders of this great nation.

Accordingly, Dr. Fishman and Ms. Giannelli respectfully move your Honor to grant this dismissal of Counts 1-2 with prejudice.

Respectfully Submitted,

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